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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/020,331                        | 12/12/2001  | Michael T. Milbocker | PRAXIS-5            | 9980             |
| 21127                             | 7590        | 02/03/2011           | EXAMINER            |                  |
| RISSMAN HENDRICKS & OLIVERIO, LLP |             |                      | FUBARA, BLESSING M  |                  |
| 100 Cambridge Street              |             |                      |                     |                  |
| Suite 2101                        |             |                      | ART UNIT            | PAPER NUMBER     |
| BOSTON, MA 02114                  |             |                      | 1613                |                  |
|                                   |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|                                   |             |                      | 02/03/2011          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mbien-aime@rhoiplaw.com  
cjoseph@rhoiplaw.com  
info@rhoiplaw.com

|                              |                        |                       |
|------------------------------|------------------------|-----------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |
|                              | 10/020,331             | MILBOCKER, MICHAEL T. |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |
|                              | BLESSING M. FUBARA     | 1613                  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 December 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,7-11 and 51-53 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,7-11 and 51-53 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

1. The examiner acknowledges receipt of request for extension of time, remarks and request for reconsideration and declaration under 37 CFR 1.132 by Dr. Michael T. Milbocker, all filed 12/08/2010. No claim is amended. Claims 1, 7-11 and 51-53 are pending.

### **Claim Rejections - 35 USC § 102/103**

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 7-11 and 51-53 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wood (US 4,241,537) for reasons of record and reiterated herein below.

4. Claim 1 incorporates the limitations of claims 2 (for trifunctional polyol), 6 (polyisocyanate is selected from toluene diisocyanate and isophorone diisocyanate), and claim 10. Claim 1 also recites molecular weight of the alkylene oxide polymers. Part of the limitation of claim 9 was recaptured in previously presented claim 53.

5. Wood discloses a composition comprising isocyanate terminated polyurethane prepolymer (abstract; column 2, lines 61-65) that comprises at least three functional groups (column 5, lines 37-40); the mixture forms a gel (column 5, lines 10 and 11); the polymer contains ethylene oxide (EO) units and propylene oxide (PO) units with specific requirement that

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the PO unit be present at less than 50% (column 6, lines 37-39); preferably the hydrophobic PO is at about 30% and the EO is greater than about 70% preferably (column 7, lines 27, 28, 35-37); the isocyanates are present as toluene-2,4-diisocyanate and toluene-2,6-diisocyanate at a ratio of 80:20 (column 8, lines 15, 16; column 10, lines 57 and 58); isophorone diisocyanate is also present or employed (column 8, line 56); the polymer formed between PO and EO in the presence of the isocyanates is block, random or both (column 7, line 15). The ratio of the EO to PO, the number of functionalities of at least 3 as stated above, the amount of water which is present at 50-95% (column 3, lines 39-41) meet the limitations of claims 1 and 51. Toluene-2,6-diisocyanate meets claims 7, 11; isophorone diisocyanate meets claims 8, 10 and 11; isocyanates present as toluene-2,4-diisocyanate and toluene-2,6-diisocyanate at a ratio of 80:20 as described above meet claim 9. The concentration of the isocyanate is low (column 6, lines 6-14) resulting in minimal free isocyanate. Wood contemplates copolymerizing EO with PO in the presence of polyols such as trimethylolpropane (column 7, lines 55-58). The silence of Wood on the presence of free isocyanate in the composition indicates composition that is free of the NCO or minimal amount present since the starting amount is low at 2 meq/g and claim 53 is thus met. Wood does not add catalyst to the composition so that the presence of low molecular weight polyisocyanate meets claim 52 since the functionality is at least 3. Wood teaches that the number average molecular weight of the pre-polymer is at least 3000 (column 5, lines 51-53), which intersects points within the recited range meeting the molecular weight requirement. Therefore, Wood anticipates the claims. In the alternate, the silence of Wood on the presence of free isocyanate in the composition indicates the composition is free of NCO or is present in

minimal amounts. Therefore, taking the general teaching of the reference, it would be *prima facie* obvious that the amount of the isocyanate remaining is very minimal.

### **Response to Arguments**

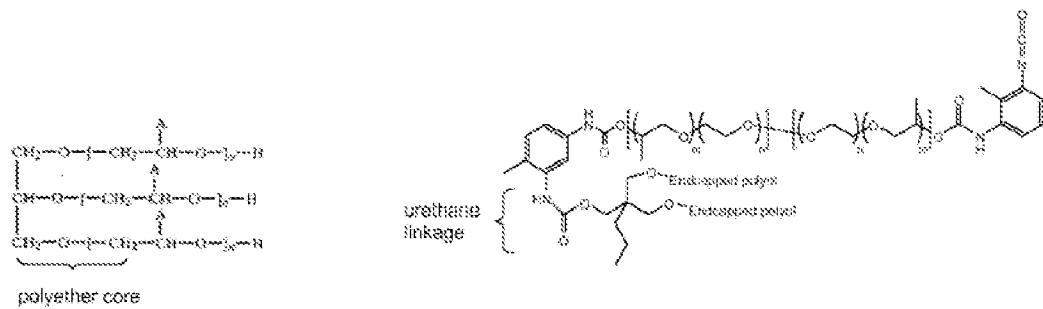
6. Applicant's arguments filed 12/08/2010 have been fully considered but they are not persuasive.

7. Applicant argues that the product formed in Wood contains ether linkages at the trimethylolpropane core and that the structure on column 6, lines 45-60 confirms that the trimethylolpropane is bonded to the three copolyol via ether linkages and not urethane linkages.

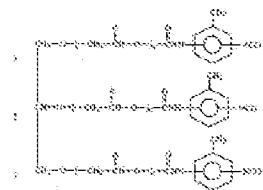
8. Response: The examiner disagrees because the goal of Wood is to form polyurethane hydrogel (see the title; column 2, lines 61-65). Furthermore the structure in column 6, lines 45-60 contains urethane linkages and not ether linkages. The instant claim is a broad copolymer polyol that is formed from “a reaction between a polyethylene/polypropylene oxide diol of between 800 and 5,000 MW, trimethylolpropane, and the low molecular weight polyisocyanate, and wherein at least 1% of said composition by weight, but not more than 5% of said composition by weight, comprises the low molecular weight polyisocyanate as a free polyisocyanate; and wherein on average in the composition, 10% to 30% of the monomers of said block copolymer polyol are derived from propylene oxide monomers, and the rest of the monomers are ethylene oxide derived monomers; characterized in that after polymerization, upon exposure to tissue or water, the adhesive composition forms a hydrogel comprising, after equilibration with water or aqueous fluids, greater than 50% water by volume; and wherein the composition polymerizes *in situ* upon exposure to water and application to tissue, without requiring the addition of a catalyst.” These are the same components in wood.

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9. Applicant has represented the structure of Wood as shown in the left structure below as being from column 6, lines 23-30 stating that the examiner referred to that structure; applicant also represented the structure that can be derived from claim 1 by the structure on the right below:



However, the structure designated by applicant to be the structure of Wood is the prepolymer from which the polyurethane is formed with diisocyanate as found in column 6, lines 45-62, which was the structure examiner referred. Further, it is respectfully noted that the polyether applicant refers is the prepolymer that is derived from glycerol such that the reaction of that prepolymer with the diisocyanate would necessarily form the polyurethane shown below and different from that represented by applicant above where the polyol is trimethylolpropane (structure on right above):



Product derived from trifunction polyol and diisocyanate  
column 6, lines 41-62 of Wood

But, when trimethylolpropane (see column 7, line 58 of Wood) is chain extended with EO or PO or EO/PO copolymer and reacted with diisocyanate, the polyurethane of applicant would also be expected to form.

Further, Wood did not call its prepolymer the core of the urethane and the claims have not recited trimethylolpropane core bonded to urethane linkages. Therefore, applicant's argument that the core of Wood differs from the core of the claimed hydrogel is not persuasive --- Wood contemplates extending the chain of trimethylolpropane with EO/PO copolymer and reacting that with the diisocyanate just as the claims.

10. With respect to section 11 of the office action of 06/08/2010, applicant disagrees with the office actions response to applicant's arguments of 05/04/2010 in that applicant strongly believes that a two step process is not needed to arrive at the trimethylolpropane-urethane core as per the declaration by Dr. Milbocker.

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11. Response: Claim 1, though a product by process claim is not a process claim and thus, applicant's argument of a two process in Wood is not persuasive.

12. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Applicant's attempt to use a prepolymer derived from glycerol to say that the product obtained differs from the claimed product is not persuasive since applicant has not used the trimethylolpropane that Wood desires to use in another embodiment to show that the polyurethane formed from the trimethylolpropane and EO/PO copolymer and diisocyanate is different from the product of the claims that is derived from trimethylolpropane, EO/PO copolymer and diisocyanate.

13. With respect to section 13 of the office action of 06/08/2010, applicant argues that the office action failed to account for the product by process limitation that was added by the amendment of 12/10/2008 to claim 1 and that the core in Wood is an ether while the core in the claimed product is a urethane.

14. Response: The examiner disagrees with the applicant that the office action ignored the product by process limitation because the office action specifically stated that “Wood contemplates copolymerizing EO with PO in the presence of polyols such as trimethylolpropane. Furthermore, the claim 1 does not say that the polyurethane is in the core. A review of the

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specification as filed does not describe the polyurethane linkage as being in a core and the word core cannot be located in the as filed specification.

15. Applicant's argument with respect to product by process limitation in the claims is not persuasive because, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Applicant's attempt to use a prepolymer derived from glycerol to say that the product obtained differs from the claimed product is not persuasive since applicant has not used the trimethylolpropane that Wood desires to use in another embodiment to show that the polyurethane formed from the trimethylolpropane and EO/PO copolymer and diisocyanate is different from the product of the claims that is derived from trimethylolpropane, EO/PO copolymer and diisocyanate.

16. The examiner has reconsidered the claims, the art and applicant's arguments and finds applicant's arguments unpersuasive --- the claims are anticipated or in the alternate rendered obvious by Wood.

Declaration under 37 CFR 1.132 by Dr. Michael T. Milbocker

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17. In paragraphs 6-11 of the declaration, Dr. Milbocker argues that because Wood uses a two step synthesis of polyurethane, the urethane linkage is not in the core while the urethane linkage is in the core as is expected for the claimed product that is formed in a one step/one port synthesis in the claimed product.

18. Response: The declaration under 37 CFR 1.132 filed 12/08/2010 is insufficient to overcome the rejection of claims 1, 7-11 and 51-53 based upon 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wood (US 4,241,537) as set forth in the last Office action because: the declaration is not commensurate with the scope of the claims that do not recite that the urethane linkage is in the core of the polymer composition. While the claims are directed to product by process claims, the claims are not strict process claims, while the claims do not recite that the urethane linkage in the polymer is in the core, the expert opinion of the declarant does not take the place of factual showing that the structure of the Wood polyurethane is different from the structure of the polymer of the claims.

19. With respect to paragraph 12 of the declaration, the expert opinion that the polyurethane in Wood is at the terminus of each branch emanating from the core since Wood forms a polyether core before adding the isocyanate and that this process would not result in polyurethanes at the core.

20. Response: The presence of polyurethane in the core is not commensurate with the scope of the claimed composition where the claim does not recite a core and the presence of urethane in a core. Further, expert opinion in the declaration does not take the place of factually showing that reaction between EO/PO and trimethylolpropane and isocyanate results in a polyurethane polymer in which the urethane linkages are in the core while reacting EO/PO copolymer with

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trimethylolpropane and further adding isocyanate to that reaction mixture produces a polyurethane polymer in which the urethane linkages are on the terminus of each branch "emanating from the core."

21. No claim is allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1618